REMARKS

Applicant has amended claim 103 and cancelled claim 104-106, 125 without prejudice in order to expedite prosecution and advance the case towards issuance. Please add new claims 140 - 143. A marked up copy of the amended claims is attached hereto on the sheet entitled **"VERSION WITH MARKINGS TO SHOW CHANGES MADE"**.

I. The Written Description Rejection

Claims 103-139 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking sufficient written description. The Examiner argues that the specification fails to provide sufficient relevant identifying characteristics that identify members of the genus of antibodies that bind gp55 antigens.

Applicant respectfully traverses to the extent the rejection may be held to apply to the claims as amended. Applicant notes that the *Fiers v. Sugano* recognizes that a chemical material can be claimed by means of a process and that conception can occur (and thus the written description requirement can be satisfied) when one is able to describe the chemical material by its method of preparation. *See Fiers v. Sugano*, 25 U.S.P.Q.2d 1601, 1604-1605 (Fed. Cir. 1993). The gp55 antigen is not an intended limitation of the claim and it is not in claim 103 as amended (see new claim 141 that relates to binding sites for the gp55 antigen). Here, the claimed invention does not claim a specific antigen or isolation of a specific antigen, but instead, claims a composition comprising an antibody that binds specifically to an antigen on the surface of the targeted carcinoma or lymphoma. The chemical identity of the claimed antigenic binding site is clearly described by the process of isolation. Methods for isolating an antibody that binds specifically to an antigen on the surface of a carcinoma or lymphoma are well known in the art

and are sufficiently disclosed in the specification (e.g., pages 10-11, 25-26, 32, 35-36). Thus, the written description requirement is satisfied by disclosing the antibody and the method of preparation. Accordingly, the rejection is traversed and Applicant respectfully requests that the Examiner reconsider and withdraw the rejection.

II. The Enablement Rejection

Claims 103-139 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled. The Examiner indicates that use of non-irradiated tumor cells is not enabled and that there is insufficient guidance in the specification as to how to make and/or use an anti-gp55 monoclonal antibody. Respectfully, this rejection is traversed as follows:

In order to expedite prosecution and advance the case towards issuance, Applicant has amended the claims to require that the tumor cells are irradiated. Furthermore, as explained above, Applicant believes sufficient disclosure exists in the specification enabling one skilled in the art to isolate and appropriate antigen on the target carcinoma or lymphoma cell (e.g., pages 10-11, 25-26, 32, 35-36). One skilled in the art can make and use the claimed invention, including the antibodies made by the recited method, without undue experimentation.

The Examiner also argues that the disclosure of working examples with regards to the use of the instant invention for treating cancer in vivo in humans or in any mammal is necessary to enablement. Applicant respectfully traverses. The specification discloses that the claimed invention is to be used in "a patient mammal (including a human)" (page 7, lines 7-8) and gives several prophetic examples based on the working examples of mice. (pages 19 - 29). Prophetic examples amply enable the claimed invention. MPEP ¶608.01(D) ("prophetic examples are permitted in patent applications.") The disclosure of working examples in mice in conjunction

with the prophetic examples with respect to use for treating cancer in vivo in humans or in any mammal enable one skilled in the art to make or use the claimed invention. *Atlas powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569 (Fed. Cir. 1984) ("prophetic examples of the specification were based on actual experiments that were slightly modified in the patent to reflect what the inventor believed to be optimum, and hence, they would be helpful in enabling someone to make the invention.")

Examiner further argues that the specification does not disclose that the monoclonal antibody is readily available to the public or readily obtainable by a repeatable method. Applicant respectfully traverses and directs the Examiner's attention to page 10 of the specification and the references incorporated therein. Moreover, monoclonal antibody used in the claimed invention is known and readily available to the public.

In view of the above, Applicant respectfully submits that the rejection has been traversed. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

III. The Provisional Double Patenting Rejections

Claims 103-139, stand provisionally rejected under the judicially created doctrine of obviousness type double patenting as allegedly being unpatentable over claims 70-100, of co-pending application no. 09/216,062.

In view of the amended claim, this rejection is now rendered moot.

IV. The New Matter Rejection

Claims 123, 124, and 125 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing new matter. Applicant respectfully traverses and directs the Examiner's attention to page 8, lines 1-6 of the specification. On page 8, the specification discloses the specific percentages of antibody attached to the targeted diseased cells in claims 123. "In a preferred embodiment, substantially all (e.g., > 80%, preferably >90%, more preferably >95%) the bridge molecules in the immunogenic composition are attached to the autologous target diseased cells." The limitations in question are set forth in the passage noted above and thus the claims are fully supported by the application as filed and add no new matter. Applicant respectfully requests that the Examiner withdraw this rejection in view of this traverse.

V. The Indefiniteness Rejection

Claims 103-129 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Applicant respectfully traverses to the extent the rejection may be held to apply to the claims as amended. In particular the Examiner's concern regarding the phrase "substantially free" in claim 125 is now moot in view of the fact that Applicant has cancelled claim 125 without prejudice in order to expedite prosecution and advance the case towards issuance. Furthermore, the Examiner's concerns regarding the antibodies which bind gp55 antigens in claim 103 is also moot in view of the amendment to claim 103 which omits the cited limitation. Moreover, the claimed antigenic binding site is clearly identified by its physical property and method of preparation, which is well known in the art. As the Examiner noted with respect to monoclonal antibody (Office Action dated 6/14/01, page 5), "the antibody is required to practice

the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method." Similarly, the antigenic binding site is required to practice the invention and isolation thereof is known and readily available to the public. One skilled in the art would have no difficulty understanding the claim as amended. In view of the above, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection.

CONCLUSION

Applicant believes that this Response will now place the application in condition for allowance. If the amount enclosed is incorrect, please charge or credit Baker & McKenzie Deposit Account No. 02-0410 in the appropriate amount. Should any issues remain unresolved, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claim 103 was amended, claims 102-104, and 125 was cancelled without prejudice, and new claims 140-143 were added as follows:

103. (Amended) An isolated, enriched or purified immunogenic composition comprising:

[(a)] one or more autologous target carcinoma or lymphoma cells [hepatocellular carcinoma, lymphoma or colorectal carcinoma] which have been irradiated and treated [with IFN-γ, TNF-α, or both] in vitro [and which express one or more CD28 or 4-1-BB] wherein said target carcinoma or lymphoma cells express one or more primary or costimulatory T cell activation molecules at a level higher than [said one or more CD28 or 4-1BB] the amount of primary or costimulatory T cell activation molecules expressed from [hepatocellular carcinoma, lymphoma or colorectal carcinoma] carcinoma or lymphoma cells without treatment in a patient mammal;

[(b) one or more antibodies comprising one or more binding sites for said one or more CD28 or 4-1BB molecules on the surface of T cells in said patient mammal, wherein said one or more antibodies further comprise one or more antigen binding sites for one or more gp55 antigens on the surface of said one or more target hepatocellular carcinoma, lymphoma or colorectal carcinoma cells, wherein one or more of said one or more antibodies are attached to one or more of said one or more target hepatocellular carcinoma, lymphoma or colorectal carcinoma cells at said one or more gp55 antigens.]

one or more antibodies wherein said antibodies further bind to an antigenic binding site on the surface of said one or more target carcinoma or lymphoma cells;

one or more primary or costimulatory T cell activation molecules on the surface of T cells in said patient mammal; and

a bridge molecule binding said antibodies and said primary or costimulatory T cell activation molecules on the surface of T cells of said patient mammal.

-- 140. The composition of claim 103, wherein said target carcinoma cells further comprise hepatocellular carcinoma or colorectal carcinoma cells.

141. The composition of claim 103, wherein said antibodies further comprise one or more binding sites for antigen gp55.

142. The composition of claim 103, wherein said primary or costimulatory T cell activation molecules bind to CD28 or 4-1BB.

143. The composition of claim 103, wherein said bridge molecule further comprises bispecific monoclonal antibody.--